BIONOSTICS
FERRARIS
Quality Solutions

JAN 26 2006

K053327

510(k) Summary[1]

(a) (1) **Submitter's name, address**

Bionostics, Inc.
7 Jackson Road
Devens, MA 01434

Contact Person

Kathleen Storro
Sr.Director, QA & Regulatory Affairs
(978) 772-7070 x 220

Date of preparation of this summary: 30 November 2005

(2) **Device trade or proprietary name:** Oxygen Saturation Control

Device common or usual name or classification name:

Oxygen Saturation Control

PRODUCT NOMENCLATURE	CLASSIFICATION NUMBER	CLASS	PANEL
Control, Single Analyte (Assayed or Unassayed)	862.1660 (JJX)	I	Chemistry

I. Substantial Equivalence

Oxygen Saturation Control for Waters Oxicom is substantially equivalent in function, safety and efficacy to other Bionostics products for the quality control evaluation of oxygen saturation.

Comparison of Technological Characteristics with Predicate Device

Characteristic	New Device	Predicate Device	Predicate Device	Predicate Device
Name:	Oxygen Saturation Control for Waters Oxicom	Oxicom 2100 QC Filters	OPTI-Check Quality Control	Multifunction Blood Gas Control
510(k):	--	K921519	K974822	K880447
Description:	Aqueous solution containing suspended styrene beads and dyes to simulate tHb and Oxygen Saturation	1 translucent plastic (QC1) and 2 precision glass (QC2, QC3) filters with discreet absorbance values	Aqueous solution containing suspended styrene beads to simulate tHb and Oxygen Saturation	Aqueous solution containing dyes to simulate tHb andOxygen Saturation
Intended Use:	As a quality control solution for use to verify the performance of the Waters Oxicom systems for measurement of Oxygen saturation	As a means to check the calibration of the Oxicom system	As a quality control solution to verify performance of AVL OPTI for measurement including oxygen saturation and tHb	As a quality control solution for use to verify the performance of blood gas instruments for measurement including oxygen saturation and tHb
Levels:	3	3	3	3
Analytes:	Oxygen Saturation (**SO2%**)	Oxygen Saturation (**SO2%**)	pH, PCO2, PO2, Na, K, Cl, iCa, tHb, **SO2%**	pH, PCO2, PO2, Na, K, Cl, iCa, tHb, **SO2%**, MetHb%, COHb%

[1] This summary of safety and effectiveness is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

II. Description of the new device

The Waters Oxicom family of oxygen saturation meters, (2000, 2100 and 3000) utilize light emitting diodes and a solid state detector to measure the absorbance of light by a whole blood sample contained in an optically clear cuvette at 2 wavelengths. The amount of IR light absorbed by the blood is relatively independent of the blood's oxygenation. However, RED light absorption or optical density is strongly dependent on the oxygen saturation. The ratio of the optical densities at the two wavelengths is used to calculate the functional oxygen saturation. The Quality Control (QC) filters supplied with the Oxicom systems allows the user to check the calibration of the Oxicom. The set of filters consist of one translucent plastic filter (QC1), and two precision glass filters (QC2 and QC3). The optical densities of these filters are stored in the unit's microprocessor. When inserted into the sample chamber the Oxicom measures the optical density and compares it to the value stored. If the optical densities match, the display will read a %Sat value.

The solutions in the 3-level Oxicom Control are a suspension of polystyrene beads in an inorganic, aqueous buffer solution with dyes to simulate the absorbance of light equivalent to that of whole blood at a range of oxygen saturation clinically relevant.

Oxicom Control provides a convenient method of performing periodic QC checks for laboratories selecting to measure liquid QC material as a part of their quality assurance program. The product is packaged in a glass bottle.

Oxicom Control is a non-hazardous liquid control solution containing no human biological materials and requires no reconstitution prior to use.

(5) Intended use of the device

Oxicom Control is intended for use as a quality control solution to evaluate Oxicom measurement at a range of clinically relevant oxygen saturation values.

Oxicom Control is a three-level, liquid control solution with dyes and polystyrene beads to provide absorbance relative to a range of oxygen saturation values. The concentration of beads and dyes are optimized for the Waters Oxicom Systems to provide an improved range of oxygen saturation values in comparison to the existing, filter systems, and handling and measurement essentially equivalent to the measurement of whole blood.

(b) (1) Summary of non-clinical tests submitted with the premarket notification for the device.

Tests were conducted to verify specific performance requirements:

a) Closed bottle stability
b) Stability after opening
c) Correlation to predicate device
d) Test precision and range

(b) (2) Summary of clinical tests submitted with the premarket notification for the device.

N/A

(b) (3) Conclusions drawn from the clinical and non-clinical trials.

Comparison of technological characteristics, formulation and intended use to predicate devices listed in this summary support the claim of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 26 2006

Ms. Kathleen Storro
Sr. Director, QA & Regulatory Affairs
Bionostics, Inc.
7 Jackson Road
Devens, MA 01434

Re: k053327
Trade/Device Name: Waters Oxicom Control
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJX
Dated: November 30, 2005
Received: December 1, 2005

Dear Ms. Storro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053327

Device Name: Waters Oxicom Control

Indications For Use:

Oxicom Control is intended to be used to monitor and evaluate the analytical performance of the Waters Oxicom models 2000, 2100 and 3000 oxygen saturation meters for the measurement of oxygen saturation. The use of quality control materials is indicated as an objective assessment of the precision of methods and techniques in use and is an integral part of good laboratory practice. The three levels of oxygen saturation provided by the controls allow performance monitoring within the clinically important range.

For *In Vitro* Diagnostic Use

Prescription Use ___√___ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

0

Ann Chaplin
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K053327